January 15, 2003

James A. Deyo, D.V.M., Ph.D., D.A.B.T.
Technical Associate
Product Safety and Stewardship
Eastman Chemical Company
P.O. Box 511
Kingsport, TN 37662

Dear Dr. Deyo:

We have conducted an initial review of the test plan for Aldehydes, C4 Self-Condensation Products, High-Boiling Fraction submitted by Eastman Chemical Company as part of their commitment under the HPV Challenge Program.

Our preliminary analysis focused on the overall approach. We have concluded that EPA is unable to continue its evaluation for the following reasons.

1. The Test Plan Summary states that the company intends to address the SIDS endpoints with existing data already generated on either the constituents of Solvent C or their expected metabolites in conjunction with predictive computer models. There is a later statement that Eastman believes the data identified to date that are presently available to EPA and the general public fulfill the hazard screening needs. However, it's also stated that some needed data are still "in the process of being generated." It is not clear from the test plan which data are available and which are prospective. Similarly, there is no indication of which of the available data have been judged adequate in the "other programs" cited and which are still pending evaluation.

2. Although the test plan states that seven of the major Solvent C components are or will be adequately characterized as part of the OECD, ICCA, or HPV programs and that three other components are well characterized because of their respective uses in food, as an insect repellant, and as a pesticide inert, it does not discuss the potential physicochemical, environmental, and toxicological properties of Solvent C. The plan suggests that the hazard potential of the components of Solvent C will "likely represent the potential hazards" of Solvent C, but it does not present or summarize any of this information. The plan does not discuss how to use the information on the components to describe the hazard potential of Solvent C nor why this approach is an adequate substitute for testing Solvent C itself. As the test plan states, "Since Solvent C consists of many chemicals present in varying amounts it is not known how the various SIDS endpoints will be affected by their presence as a mixture." This implies that testing the mixture may be the preferred option, but there is no expanded discussion of the issue.

3. The company did not submit robust summaries for studies stated in the test plan to be available for 2-ethyl-1,3-hexanediol. "Information available in the published literature" needs to be summarized by the submitter. Summaries should follow EPA Challenge Program guidance.

4. The test plan characterizes di-2-ethylhexyl ether, the Solvent C component with by far the highest percentage range, as having no data other than an LD50. There is no discussion of the impact of this potentially significant data gap.

5. The test plan states that "Eastman believes that the obligations of our commitment to this chemical in the HPV Challenge Program have been completed through this submission." This is not the case, because not only does the test plan fail to explain how it will use the combined data, but once all testing and program reviews are completed the submitter needs to follow through with a final analysis of the available data and how they characterize the properties of the mixture.

6. A brief description of the manufacturing process would help reviewers to understand the character of this complex mixture and the adequacy of the composition description.

I encourage Eastman to take the necessary steps to enhance the submission. We are prepared to proceed with the review as soon as we get your response.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the HPV Challenge Program Web site "Submit Technical Questions" button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: C. Auer
A. Abramson
W. Penberthy
M. E. Weber